IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

SCOTT PURCEL and PAMELA PURCEL, individually, and as Next Friend of B.P, a Minor,	§	
	§	
	§	CIVIL ACTION NO.
Plaintiffs,	§	3:07-CV-1777-M
	§	
v.	§	
	§	
ADVANCED BIONICS CORPORATION,	§	
	§	
Defendant.	§	

AMENDED MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Advanced Bionics Corporation's Motion for Summary Judgment or Partial Summary Judgment [Docket Entry #121]. For the reasons stated below, the Motion is **GRANTED** in part and **DENIED** in part.

I. STATEMENT OF FACTS

B.P., who is deaf, was twenty months old when, in July of 2005, surgeons implanted in his ears the HiRes90k, manufactured by Defendant Advanced Bionics Corporation ("Bionics"). This cochlear implant is an electronic device that electronically stimulates nerves in the inner ear, sending electrical impulses to the brain, which, over time, are interpreted as sound. An internal device is surgically placed inside the skull, behind the ear, and an external sound processor is worn on the outside of the ear. The safety and efficacy of the HiRes90k are the focal points of the suit brought by Plaintiffs, who are B.P.'s parents.

Plaintiffs' suit centers on a single component of the HiRes90k--a "feed-thru" used to connect the device's internal electrical circuitry to its external components, manufactured by Astro Seal, Inc. ("Astro Seal"). To be effective, the feed-thru had to be waterproof and hermetically sealed, so it would not contain excessive moisture.

Following implantation, audiologists worked with B.P. to configure the devices to maximize their effectiveness. However, B.P. did not hear the full range of sounds expected, and failed to achieve language development milestones. B.P. vocalized an abnormal, high-pitched hum only when the external part of each device was turned on, and he resisted wearing the external devices. He went to Bionics' headquarters and met with Bionics' representatives, who made programming changes to the devices, but B.P. still hummed abnormally and could not detect certain sounds. Bionics assured Plaintiffs that the devices were not malfunctioning and that the problem somehow originated with B.P.[1] However, in March 2006, Bionics voluntarily recalled all unimplanted HiRes90k devices with Astro Seal feed-thrus.

B.P. underwent two surgeries to remove the Bionics cochlear implants and re-implant devices from another manufacturer. Bionics tested the removed devices and determined that their moisture levels were 3.0312% and 2.159%--well above the moisture level of 0.5% provided as the maximum in Bionics' manufacturing specifications, which had been approved by the Food and Drug Administration ("FDA"). After implantation of the new devices, B.P. did not hum abnormally and was positive about wearing the external devices, and his language development skills improved.

A. Violations of Federal Requirements

1. Premarket Approval

Cochlear implants are Class III devices under the FDA's regulatory scheme. In 1996, the FDA gave premarket approval ("PMA") for Bionics' "Clarion Multi-Strategy Cochlear Implant System." In 2003, the FDA gave supplemental premarket approval for the HiRes90k, an

[1] Ps' App. at 129A.

improved version of the Clarion implant. Under 21 U.S.C. § 351(f), a Class III device sold without the requisite FDA approvals is considered "adulterated."[2]

In July 2003, Bionics obtained premarket approval for Pacific Aerospace & Electronics, Inc. to manufacture feed-thrus for the HiRes90k. Without obtaining supplemental FDA approval, Bionics then contracted with Astro Seal to manufacture the feed-thrus. Plaintiffs assert that excessive moisture in the devices, caused by a hermeticity issue with the Astro Seal feed-thrus, led to their failure.

2. Current Good Manufacturing Practices Requirements

The FDA requires manufacturers of Class III devices to comply with Current Good Manufacturing Practices ("CGMP"). Class III devices not satisfying CGMP requirements are adulterated.[3] Plaintiffs point to inspection reports and warning letters issued and sent by the FDA to Bionics, noting at least eighteen violations of specific CGMP requirements between 2001 and 2005. These violations focused on moisture problems in the HiRes90k's circuitry, Bionics' failure to conduct management reviews with sufficient frequency, and Bionics' failure to establish required auditing, training, operating, testing, and quality assurance procedures.[4]

3. FDA Enforcement Action

In November 2006, the FDA filed an administrative complaint, seeking civil penalties from Bionics and its President and Chief Executive Officer, Jeffrey Greiner, for violations of PMA and CGMP requirements. The FDA alleged that Bionics failed to notify the FDA of its new feed-thru supplier, and neglected to validate the continued safety and effectiveness of the HiRes90k through appropriate testing. The FDA also claimed that excessive moisture in the HiRes90k exposed patients to the risk of device failure, corrective surgery, and further hearing

[2] *See* 21 C.F.R. § 814.39(a).
[3] *See* 21 U.S.C. § 351(h).
[4] Ps' App. at 332-34, 336-46.

loss.[5] The FDA contended that Bionics and Greiner shipped adulterated devices into interstate commerce, and thereby committed at least seventy-four acts prohibited under 21 U.S.C. § 331(a).[6] In exchange for dismissal of the FDA's complaint, Bionics paid a $1.1 million fine and Greiner paid a $75,000 fine.

B. Plaintiffs' Claims

Plaintiffs' Second Amended Complaint claims negligence, products liability, fraud, negligent misrepresentation, fraud by nondisclosure, and breach of express and implied warranties. Plaintiffs' state law claims are largely based on their assertion that the HiRes90k devices were defective and adulterated under 21 U.S.C. § 351(f), (h) because: (1) Astro Seal was not an approved manufacturer of the feed-thrus in the HiRes90k; (2) Bionics did not obtain premarket approval for design modifications made to the HiRes90k; and (3) manufacturing processes for the HiRes90k did not comply with CGMP requirements. Bionics seeks summary judgment on all of Plaintiffs' claims.

II. ANALYSIS

A. FDA Regulation and Preemption

1. General Regulatory Framework

Medical devices intended for human use are regulated by the FDA and placed into one of three classes, pursuant to the 1976 Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c *et seq.*, to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.* Class I medical devices, which include elastic bandages and examination gloves, are subject to "general controls," such as labeling requirements, and receive the lowest level of oversight.[7] Powered wheelchairs and surgical drapes are examples of Class II devices, which are subject to additional

[5] Compl. at Ex. B.
[6] Ps' App. at 293.
[7] *Riegel v. Medtronic*, 552 U.S. 312, 316 (2008) (citing 21 U.S.C. § 360c(a)(1)(A)).

"special controls," such as performance standards and postmarket surveillance measures.[8] Class III devices, such as the HiRes90k, receive the most oversight:

> In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury."[9]

Some stents, bone screws, balloon catheters, artificial hips, and replacement heart valves are also Class III devices.

Certain Class III devices, such as the HiRes90k, must undergo a rigorous premarket approval process, during which the manufacturer typically submits a multivolume application, which includes full reports of all studies of the safety and effectiveness of the device, full descriptions of the components and manufacturing methods for the device, and samples of the device.[10] The FDA spends considerable time reviewing applications for such Class III devices, and only grants approval if it finds a "reasonable assurance" of the device's "safety and effectiveness."[11] The FDA is to weigh the "probable benefit to health from the use of the device against any probable risk of injury or illness from such use."[12] Once the FDA has granted premarket approval, the device must be manufactured with "almost no deviations from the specifications in its approval application."[13] Any modification affecting the safety or effectiveness of an approved device, including any change of the facility manufacturing such a device, must receive supplemental premarket approval.[14] Changes in the "performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the

[8] *Id.* at 316-17 (citing 21 U.S.C. § 360c(a)(1)(B)).
[9] *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).
[10] *Id.* at 317-18 (citing 21 U.S.C. § 360e(c)(1)).
[11] *Id.* at 318 (citing 21 U.S.C. § 360e(d)).
[12] *Id.* (quoting 21 U.S.C. § 360c(a)(2)(C)).
[13] *Id.* at 323.
[14] 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a)(3).

device" also require FDA approval.[15] Supplemental premarket approval is evaluated largely by the same procedures, criteria, and extensive scrutiny as the original PMA process.[16]

Because Bionics did not obtain supplemental premarket approval for Astro Seal feed-thrus and violated CGMP requirements, the devices are considered adulterated under the applicable statutory and regulatory scheme.[17] The FDCA prohibits the introduction of adulterated devices into interstate commerce, and empowers the FDA to enjoin and penalize the sale of adulterated devices.[18]

2. Express and Implied Preemption

The MDA contains an express preemption provision, 21 U.S.C. § 360k(a), which states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

In *Riegel v. Medtronic*, the Supreme Court considered the case of a plaintiff who was severely injured when a balloon catheter in his right coronary artery burst after his physicians inflated it beyond its rated pressure.[19] The plaintiff alleged that the catheter was defectively designed, labeled, and manufactured in a manner that violated New York common law, but did not timely argue that the device violated relevant federal requirements.[20] The Supreme Court interpreted § 360k(a), holding that state requirements are expressly preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by

[15] 21 C.F.R. § 814.39(a)(6).
[16] *Riegel*, 552 U.S. at 319; *Hughes v. Cook*, 452 F. Supp. 2d 832, 836 (W.D. Tenn. 2006).
[17] *See* 21 U.S.C. § 351(f), (h); 21 C.F.R. § 814.39.
[18] *See* 21 U.S.C. §§ 331(a), 332, 333.
[19] 552 U.S. at 320.
[20] *Id.* at 320, 330.

federal law.[21] The Court commented that state law claims premised on a violation of FDA regulations are "parallel" to federal requirements, and are not expressly preempted by § 360k(a).[22] In *Horowitz v. Stryker Corp.*, the Eastern District of New York described the three-part test a court must use to determine whether a claim is preempted by the MDA:

> First, it must find that federal requirements are imposed on the particular medical device. If so, then the court must determine whether the plaintiff's claims are based on a state requirement that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Finally, such claims will be preempted where they impose requirements that are either different from, or in addition to, the federal regulations.[23]

Because Plaintiffs' claims relate to the safety and efficacy of federally regulated Class III devices, the remaining issue is whether Plaintiffs' claims are parallel.

The parties dispute whether the fact that the devices were adulterated under federal law must be causally related to B.P.'s injuries in order for the state claims to survive preemption. Plaintiffs argue that the fact of adulteration is merely asserted as a part of parallel state law claims.[24] Bionics contends that Plaintiffs must show that the alleged statutory and regulatory violations, coupled with a defect, caused B.P.'s injuries.[25] As the *Horowitz* court explained, "in order to survive preemption under the MDA a plaintiff must demonstrate a cognizable link between the defendant's federal violations and plaintiff's injury."[26] For example, to assert

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[21] *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)).
[22] *Id*.
[23] 613 F. Supp. 2d 271, 279 (E.D.N.Y. 2009).
[24] Ps' Resp. at 12.
[25] D's Mot. at 12.
[26] 613 F. Supp. 2d at 282; *see also Anthony v. Stryker Corp.*, No. 1:09-CV-2343, 2010 WL 1387790, at *4 (N.D. Ohio Mar. 31, 2010) (noting that the plaintiff did not plead any facts supporting an inference that noncompliance with FDA regulations led to his injury); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (holding that, to state a plausible parallel claim, a plaintiff must show a link between the specific federal violation and the plaintiff's injury); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776, 789 (D. Minn. 2009).

parallel negligence and products liability claims, Plaintiffs must show that the manufacturing process violated federal requirements, thereby causing the devices to be defective.[27]

On August 13, 2008, this Court denied Bionics' Motion for Judgment on the Pleadings, and held that Plaintiffs' products liability and implied warranty of merchantability claims are not expressly preempted by the MDA.[28] In light of recent cases, Bionics resurrects its argument that Plaintiffs' claims are preempted.[29] Although several courts considering preemption issues after this Court's initial ruling found facts in their cases to be distinguishable from those here, none determined that this Court erred in its holding.[30] State law claims for damages that are premised on a violation of federal law are parallel to federal requirements.[31] This Court concluded, and still concludes, that properly pleaded state law claims asserting that a particular Class III device was manufactured in violation of PMA specifications or CGMP requirements are not preempted.[32] After considering recent cases, the Court still concludes that Plaintiffs' products

[27] *See Horowitz*, 613 F. Supp. 2d at 284 ("Without more specific allegations explaining how defendants' manufacturing process was in violation of federal requirements so that the device was defective, plaintiff's claim falls directly within the MDA's preemption provision.").
[28] *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777-M, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008).
[29] D's Reply at 12. *See, e.g.*, *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) ("In the ten months following *Riegel*, courts across the country have applied Section 360(k) broadly, preempting all manner of claims . . . .").
[30] *See, e.g.*, *Ilarraza*, 677 F. Supp. 2d at 589 (citing *Purcel* for the proposition that it is possible to state a plausible parallel claim at the pleading stage); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 532 (S.D. Tex. 2009); *Horowitz*, 613 F. Supp. 2d at 281-82 (noting that *Purcel* does not conflict with the holdings in *Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008) or *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (D. Colo. 2008)).
[31] *See Ilarraza*, 677 F. Supp. 2d at 585; *In re Medtronic*, 592 F. Supp. 2d at 1152 ("[*R*]*iegel* left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted.").
[32] *See Ilarraza*, 677 F. Supp. 2d at 589 ("Contrary to the notion that the court's holding here will make it impossible to state a plausible parallel claim at the pleading stage, the court contrasts the facts and pleadings in cases that have, indeed, stated such claims. . . . [T]he pleading with respect to the modification in *Purcel* alleged that defendant violated a particular federal specification referring to the device at issue."); *Williams v. Allergan USA, Inc.*, No. CV-09-1160-PHX-GMS, 2009 WL 3294873, at *4 (D. Ariz. Oct. 14, 2009); *In re Medtronic*, 592 F. Supp. 2d at 1161 n.17 ("[A]n adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications can survive preemption."); *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 800-01 (W.D. La. 2008); *Stevens v. Pacesetter, Inc.*, No. 3:07-CV-3812, 2008 WL 2637417, at *1 (D.S.C. Apr. 1, 2008); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 138 (Tex. App.—Houston [1st Dist.] 2005, pet. denied).

liability and implied warranty claims are not preempted, but analyzes the implied warranty claim in more detail below.

Even if not expressly preempted, a claim premised on a violation of federal law may be *impliedly* preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, plaintiffs alleged that the manufacturer of bone screws made fraudulent representations to the FDA in the course of obtaining premarket approval, and sought damages under state tort law.[33] The Supreme Court found that state law claims alleging fraud on the FDA are impliedly preempted, because it is the FDA's responsibility to punish and deter fraud, to achieve a delicate balance of statutory objectives.[34] Consequently, it has been held that "claims asserting misrepresentations, intentional or otherwise, made to the FDA regarding Class III medical devices are preempted by federal law."[35] However, Plaintiffs do not assert that Bionics made misrepresentations to the FDA, and this Court concludes that the *Buckman* implied preemption analysis is limited to such claims.[36] Accordingly, Plaintiffs' claims are not impliedly preempted under *Buckman*.

Buckman raises one other critical issue alluded to in Defendant's briefing. In *Buckman*, the Supreme Court interpreted 21 U.S.C. § 337(a), which states: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." The Supreme Court noted that "it is the Federal Government rather than private litigants

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[33] 531 U.S. at 343.
[34] *Id.* at 348.
[35] *Hughes v. Boston Scientific Corp.*, 669 F. Supp. 2d 701, 712 (S.D. Miss. 2009); *see also Riley*, 625 F. Supp. 2d at 776-77.
[36] *See In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006) ("All plaintiffs' claims are based on state statutes or traditional tort causes of action; they seek no recovery for a fraud-on-the-FDA claim. For these reasons, the Court finds no basis in *Buckman* to find an implied preemption of plaintiffs' claims."); *see generally* Daniel W. Whitney, *Guide to Preemption of State-Law Claims against Class III PMA Medical Devices*, 65 Food & Drug L.J. 113, 122-23 (2010) (Construing *Buckman* in light of *Lohr*, *Riegel*, and the legislative history of § 360k(a) and concluding that "[s]o long as fraud-on-FDA is not alleged, the implied preemption holding of *Buckman* should have little or no application to the typical products liability action.").

who are authorized to file suit for noncompliance with the medical device provisions."[37] Accordingly, § 337(a) prevents a private litigant from enjoining, or seeking damages under federal law for, FDCA violations.[38] A defendant's conduct must give rise to liability under a parallel state law.[39] Absent a federal law violation, Plaintiffs' claims would be preempted by § 360k(a).[40] However, it is contended here that Bionics did not manufacture the HiRes90k in accordance with PMA specifications, and did not seek supplemental approval for Astro Seal to manufacture the feed-thrus, thereby depriving the FDA of an opportunity to investigate or prevent moisture problems in the devices before their sale to consumers like B.P. Rather than seeking recovery for noncompliance with federal law, in this case, federal law violations open the door for the assertion of parallel state law claims.[41]

The Court recognizes that another district court addressing similar facts has concluded that parallel state law claims seeking damages for injuries associated with adulterated devices are preempted by *Buckman* and § 337(a).[42] However, *Riegel*, the Supreme Court's most recent pronouncement on preemption of medical device claims, did not reference *Buckman* or § 337(a) when it stated that parallel state law claims would survive. Were *Buckman* and § 337(a) read to impliedly preempt properly pleaded parallel state law claims, that statement in *Riegel* would be

[37] *Buckman*, 531 U.S. at 349 n.4.
[38] *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 789-91 (3d Cir. 1999); *Riley*, 625 F. Supp. 3d at 776-77.
[39] *See Riley*, 625 F. Supp. 3d at 776-77.
[40] *See Riegel*, 552 U.S. at 330; *Williams v. Cybertronics, Inc.*, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009) ("No state common-law claim can survive if it allows a claimant to proceed without showing a departure from federal standards. There simply is no wiggle room to find otherwise."); *Riley*, 625 F. Supp. 2d at 776.
[41] *See Scott v. Pfizer Inc.*, 182 F. Appx. 312, 315 (5th Cir. 2006) (considering § 337(a) and noting that the MDA does not completely preempt state products liability law); *Riley*, 625 F. Supp. 2d at 777; *In re Medtronic*, 592 F. Supp. 2d at 1161 n.17.
[42] *See Lewkut v. Stryker Corp.*, No. 09-CV-3695, 2010 WL 1544275, at *8-9 (S.D. Tex. Apr. 16, 2010).

rendered a nullity. This Court concludes that properly pleaded parallel state law claims, except those alleging fraud on the FDA, survive express and implied preemption.[43]

Notwithstanding the general conclusions reached above, certain of Plaintiffs' claims are preempted by § 360k(a).

3. Negligence and Fraud by Nondisclosure

Plaintiffs allege that Bionics breached its duty of reasonable care, by failing to manufacture the devices within PMA specifications and by failing to warn Plaintiffs that the devices were adulterated.[44] Plaintiffs' fraud by nondisclosure claim asserts that Bionics owed a duty to the Plaintiffs to disclose that the devices were adulterated.[45] Plaintiffs cite no federal requirement obligating Bionics to warn them that the devices were adulterated. These claims of fraud by nondisclosure and negligence by failure to warn impose a requirement in addition to those approved by the FDA--the duty to warn consumers if devices are adulterated--and are therefore preempted by § 360k(a).[46] However, Plaintiffs' claim that Bionics' negligent failure to follow federal law caused B.P.'s injuries is not preempted.[47]

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[43] *See Kallal v. Ciba Vision Corp.*, No. 09-CV-3346, 2010 WL 2330365, at *3 (N.D. Ill. June 9, 2010) ("[P]laintiff has pleaded that Defendants failed to comply with federal requirements. As *Riegel* makes clear, such claims are not preempted by MDA because they would not impose different or greater requirements than those under federal law."); *Phillips v. Stryker Corp.*, No. 3:09-CV-488, 2010 WL 2270683, at *4-7 (E.D. Tenn. June 3, 2010) (holding that state law claims linking the defendant's liability to its failures to comply with FDA manufacturing regulations are not preempted).

[44] Compl. at ¶¶ 79-81.

[45] *Id.* at ¶ 119.

[46] *See Horowitz*, 613 F. Supp. 2d at 286-87 (preempting a claim based on the failure to warn about the risk of an audible noise emanating from a Class III device, because it "would clearly impose requirements different from, or in addition to, the federal regulations."); *In re Medtronic*, 592 F. Supp. 2d at 1160 ("[M]edtronic correctly notes that the FDA regulations cited by Plaintiffs *permit* a device manufacturer to give certain warnings, but Plaintiffs' failure-to-warn theory necessarily requires a showing that Medtronic was *required* to give those warnings. And, Plaintiffs have not identified in the Complaint any federal regulation, rule, or other source of obligation that would *require* such a warning to be given.") (emphasis in original).

[47] *See Prudhel v. Endologix, Inc.*, No. CIV. S-09-0661 LKK/KJM, 2009 WL 2045559, at *8 (E.D. Cal. July 9, 2009) ("[A] state law claim that requires more than mere noncompliance with federal requirements-for example, that the violation of federal requirements have been reckless or unreasonable-is not precluded, notwithstanding the fact that such a claim uses a standard that is literally 'different from' the federal requirements."); *Horowitz*, 613 F. Supp. 2d at 281 n.4, 283-84 (to avoid preemption, a negligence claim must specifically allege how a defendant's manufacturing process violated federal requirements and caused a defect).

4. Breach of Express Warranty

Plaintiffs allege that Bionics breached its express warranty under TEX. BUS. & COM. CODE ANN. § 2.313, by representing that the cochlear implants satisfied the PMA specifications.[48] Because the express warranty claim is predicated on federal law and based on Bionics' alleged representations to Plaintiffs, rather than statements that were approved or mandated by the FDA, it is not preempted by § 360k(a).[49]

5. Breach of Implied Warranty of Merchantability

Plaintiffs assert that adulteration rendered the devices unfit for their ordinary purposes and proximately caused B.P.'s injuries. To prevail on a claim for breach of the implied warranty of merchantability, a plaintiff must prove that: "(1) the defendant sold or leased the product to the plaintiff; (2) the product was unmerchantable; (3) the plaintiff notified the defendant of the breach; and (4) the plaintiff suffered injury."[50] A product is "unmerchantable" if it is "unfit for its ordinary purposes."[51] A product that is inadequate for its intended purpose or unreasonably dangerous is unfit for its ordinary purposes.[52]

Several courts have found implied warranty claims to be expressly preempted, reasoning that a jury's determination that devices were unsafe in their design or manufacture would interfere with the FDA's grant of premarket approval.[53] When the FDA has examined and

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[48] Compl. at ¶ 93.
[49] *See Horowitz*, 613 F. Supp. 2d at 285; *Riley*, 625 F. Supp. 2d at 788 ("[A] breach-of-express-warranty claim based on voluntary statements is not preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer need do nothing more than refrain from making voluntary warranties.").
[50] *Polaris Indus., Inc. v. McDonald*, 119 S.W.3d 331, 336 (Tex. App.—Tyler 2003, no pet.).
[51] TEX. BUS. & COM. CODE § 2.314(b)(3).
[52] *See, e.g.*, *Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 665 (Tex. 1999); *Church & Dwight Co., Inc. v. Huey*, 961 S.W.2d 560, 569 (Tex. App.—San Antonio 1997, pet. denied).
[53] *See Lemelle v. Stryker Orthopaedics*, No. 09-0987, 2010 WL 996523, at *5 (W.D. La. Mar. 15, 2010); *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009) ("Where, as here, an essential element of a plaintiff's claim of breach of express or implied warranty will be proof that a device granted a PMA is not safe or effective, such a contention necessarily conflicts with the FDA's contrary finding and its requirement that the device be made as approved."); *Delaney v. Stryker Orthopaedics*, No. 08-03210 (DMC), 2009 WL 564243, at *3 (D.N.J. Mar. 5, 2009); *Horowitz*, 613 F. Supp. 2d at 284-85; *In re Medtronic*, 592 F. Supp. 2d at 1164.

approved the manufacturing process for, and safety of, a device, "[a] determination that even though the product complies with the FDA requirements, it has a problem causing it to breach an implied warranty, would impose requirements different from or in addition to those imposed by the FDA."[54] Because Bionics did not seek supplemental premarket approval, the FDA did not make a premarket determination that HiRes90ks with Astro Seal feed-thrus were safe and effective. To avoid inconsistency with FDA findings, the Court looks to the FDA's warning letter and administrative complaint.[55] In a February 1, 2005 warning letter, the FDA wrote: "The presence of moisture potentially results in . . . ultimate failure of the device. . . . [P]roducts continue to be manufactured and distributed, thus exposing patients to the risk of device failure and the associated risks of surgical intervention and potential permanent loss of hearing."[56] The FDA's administrative complaint stated:

> The excessive moisture exposed patients in whom the device was implanted to the risk of device failure that can, and ultimately did, lead to explantation and re-implantation, with the resulting serious risks of surgical intervention, including anesthesia, meningitis, and permanent neurological damage. In addition, excessive moisture can lead to direct current leakage, which may result in permanent injury to the auditory nerve and loss of hearing.[57]

Because the FDA found that excessive moisture in the devices rendered them prone to failure and caused serious risks to the user's health, a jury's determination that the devices were inadequate for their intended purpose or unreasonably dangerous would not contradict the FDA or interfere with its regulatory scheme. Plaintiffs' breach of the implied warranty of merchantability claim is not preempted by § 360k(a).

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[54] *Lemelle*, 2010 WL 996523, at *7.
[55] *Cf. Horowitz*, 613 F. Supp. 2d at 284 ("The FDA warning letters never imply, and plaintiff never alleges, that defendants' federal violations caused the Trident System to be unfit in assisting patients in walking, which is the purpose for which the Trident System was created.").
[56] Ps' App. at 338.
[57] Compl. at Ex. B.

6. Fraud and Negligent Misrepresentation

Plaintiffs assert that Bionics committed fraud by falsely stating that the cochlear implants were functional, operating properly for B.P., and within PMA specifications, thus discouraging Plaintiffs from removing the implants, which delayed B.P.'s language development.[58] Plaintiffs allege that Bionics negligently misrepresented that the devices were free from defect and unadulterated, which influenced their decision to purchase and retain the cochlear implants.[59] Bionics does not contend that such representations were approved by the FDA, required by the FDA, or part of any FDA-approved label.[60] Although § 360k(a) may preempt fraud claims based on statements that were approved or required by the FDA, and § 337(a) and *Buckman* preempt claims based on fraud to the FDA, none of these preempt the *voluntary* commission of fraud to purchasers after the PMA process.[61] To hold that voluntary fraudulent statements are preempted "would turn FDA approval of some statements into a free pass to deceive consumers by making other statements."[62] Plaintiffs' fraud and negligent misrepresentation claims are not preempted.

B. Legal Standard

Summary judgment is warranted if the pleadings, discovery, disclosure materials, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.[63] A genuine issue of material fact exists when a reasonable jury could find for the non-moving party.[64] The moving party bears the initial burden of identifying those portions of the record that demonstrate the absence of a genuine issue of

[58] *Id.* at ¶¶ 102-10.
[59] *Id.* at ¶¶ 111-15.
[60] *See Riley*, 625 F. Supp. 2d at 785.
[61] *Id.* at 785-86.
[62] *Id.* at 788.
[63] Fed. R. Civ. P. 56(c).
[64] *Gates v. Tex. Dep't of Protective & Regulatory Servs.*, 537 F.3d 404, 417 (5th Cir. 2008) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

material fact.[65] Once the movant carries its initial burden, the burden shifts to the nonmovant to show that summary judgment is inappropriate, by designating specific facts beyond the pleadings that prove the existence of a genuine issue of material fact.[66] In determining whether genuine issues of material fact exist, "factual controversies are construed in the light most favorable to the nonmovant."[67]

Having found that certain of Plaintiffs' negligence, products liability, breach of express warranty, breach of implied warranty, fraud, and negligent misrepresentation claims are not preempted, the Court now determines whether such claims survive summary judgment.

C. Summary Judgment

1. Negligence and Products Liability

Bionics seeks summary judgment on Plaintiffs' negligence and products liability claims, contending that the devices were not defective and that any federal law violations were unrelated to the alleged defects. Under Texas law, the elements of negligence are: "(1) a legal duty to use due care; (2) a breach of that duty; (3) proximate causation of the resulting injury; and (4) damages."[68]

Plaintiffs allege that the sale of adulterated and defective cochlear implants proximately caused B.P.'s injuries. To prevail on a theory of products liability, a plaintiff must prove that: "(1) the defendant placed a product into the stream of commerce; (2) the product was in a defective or unreasonably dangerous condition; and (3) there was a causal connection between

[65] *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Lynch Props., Inc. v. Potomac Ins. Co.*, 140 F.3d 622, 625 (5th Cir. 1998) (citing *Celotex*, 477 U.S. at 325).
[66] *See* Fed. R. Civ. P. 56(e)(2); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Fields v. City of S. Houston*, 922 F.2d 1183, 1187 (5th Cir. 1991).
[67] *Lynch Props.*, 140 F.3d at 625 (citation omitted).
[68] *Davis v. Kroger Co.*, No. 3:07-CV-1130-L, 2010 WL 1267223, at *6 (N.D. Tex. Mar. 31, 2010) (citing *Kroger v. Elwood*, 197 S.W.3d 793, 794 (Tex. 2006)).

the defect and the plaintiff's injuries or damages."[69] A manufacturing defect exists if a "product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous."[70] A plaintiff must show that the device was defective when it left the manufacturer, and competent evidence must identify a specific defect and rule out other possible causes.[71] Product failure, standing alone, is generally not proof of a defect.[72] A plaintiff may use both direct and circumstantial evidence to establish any material fact.[73] Expert testimony is "generally encouraged if not required to establish a products liability claim."[74]

Plaintiffs presented summary judgment evidence showing that B.P.'s cochlear implants were defective. B.P. vocalized an abnormal, high-pitched hum when the external speech processors were activated, resisted wearing the external processors, and failed to reach expected language and developmental milestones.[75] Bionics' "Patient Script & FAQs" listed potential symptoms of failure as the "sudden sensation of discomfort or pain, a sudden loud noise or popping sound, and *in children, an unwillingness to wear the external processor*."[76] After implantation of the new devices, B.P. developed a positive attitude about wearing the processors, and his language development skills improved.[77] During his deposition, Bionics' Head of Quality Assurance testified as follows:

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[69] *Helen of Troy v. Zotos Corp.*, 511 F. Supp. 2d 703, 721 (W.D. Tex. 2006) (citing *Houston Lighting & Power Co. v. Reynolds*, 765 S.W.2d 784, 785 (Tex. 1988)).
[70] *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006); *see BIC Pen Corp. v. Carter*, 251 S.W.3d 500, 509 (Tex. 2008).
[71] *See Alza Corp. v. Thompson*, No. 13-07-90-CV, 2010 WL 1254610, at *9 (Tex. App.—Corpus Christi Apr. 1, 2010, no pet. h.); *see also Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 42 (Tex. 2007); *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004); *but see Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 858 (Tex. App.—Dallas 2007, pet. denied) (expressing the view that a plaintiff need not identify a specific defect, in an opinion filed before *Ledesma*).
[72] *Cooper Tire*, 204 S.W.3d at 807.
[73] *Alza*, 2010 WL 1254610, at *9 (citing *Browning-Ferris, Inc. v. Reyna*, 865 S.W.2d 925, 928 (Tex. 1993)).
[74] *Ledesma*, 242 S.W.3d at 42.
[75] Ps' App. at 84, 93, 108, 237-38.
[76] *Id.* at 250 (emphasis added).
[77] *Id.* at 138A-139A.

> I think there was something wrong with the device. . . . There's no doubt about that. When you remove the device and put in a new device and he does much better and gets up to the levels that he needs to be, that's sort of telling you there was something wrong with that device. There's no doubt in my mind about that.[78]

Bionics' Director of Reliability Engineering agreed that the devices failed to perform as intended.[79]

Evidence before the Court shows that excessive moisture in the devices caused their failure. A post-explant test performed by Bionics showed that the right-side device had a moisture level of 3.0312% and the left-side device had a moisture level of 2.159%, and Bionics then confirmed the device failure and identified the source of the moisture as inadequate sealing in the Astro Seal feed-thrus.[80] During his deposition, the CEO of Bionics, Jeffrey Greiner, was asked if he had any reason to believe that B.P.'s devices did not fail, and he responded:

> No. I think [B.P.'s] devices were – I'll use the word "defective." You know, they – they had elevated moisture. . . . We have not concluded . . . that the devices failed. But you have the fact that they had high moisture outside of our spec, and you have the fact that [B.P.] did, or has been doing, exceptionally well with these new devices. You know, both of those seem to indicate that the devices failed.[81]

On August 8, 2007, Phillip Ives, Manager of Issue Tracking for Bionics,[82] sent a letter to B.P.'s surgeon, including the analysis report for B.P.'s devices. He commented: "The slightly elevated level of moisture found inside the device cases is believed to have caused the device failure. A corrective action has been initiated which determined that the moisture problem was related to a particular feed-thru assembly."[83] Bionics' Medical Device Report to the FDA also states that each device contained moisture caused by a hermeticity issue with Astro Seal's feed-

[78] *Id.* at 84.
[79] *Id.* at 87.
[80] *Id.* at 1-6.
[81] *Id.* at 80.
[82] Ives has a Doctorate in Audiology and is a Fellow of the American Academy of Audiology.
[83] Ps' App. at 247.

thrus.[84] Although Plaintiffs' expert, Thomas J. Green, equivocated in his deposition as to the cause of the failure,[85] his declaration, correcting his deposition testimony and summarizing his findings, stated that the devices failed due to moisture entering the feed-thrus.[86]

Bionics provided the design plans and specifications for the feed-thrus to Astro Seal, which Astro Seal apparently manufactured without alteration.[87] Summary judgment evidence shows that the moisture in the devices apparently occurred during the manufacturing process at Astro Seal, for which Bionics did not seek a supplemental PMA, thereby depriving the FDA of the opportunity to assess the Astro Seal process as it related to the safety of the devices.[88] In its February 1, 2005 warning letter, the FDA advised Bionics that entrapped moisture in its implants could be the result of process deficiencies in manufacturing.[89] During a February 2007 inspection, the FDA observed that Bionics did not adequately qualify Astro Seal as its feed-thru supplier and that the devices were not tested under actual or simulated use conditions.[90] The failure to abide by manufacturing specifications and perform tests that the FDA deemed necessary to detect defects establishes a causal relationship between the federal violations and the defects.[91] Summary judgment on Plaintiffs' negligence and products liability claims is therefore denied.[92]

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[84] *Id.* at 284-87.
[85] *Compare* D's App. at 73 ("I don't know the cause of failure for the Purcel explant.") *with* Ps' App. at 228 ("I think the moisture got in through a seal that was either defective from the start of manufacturing, or was damaged during manufacturing. And I think that seal . . . allowed moisture to ingress into that device and was a cause of the failure.").
[86] Ps' App. at 134.
[87] Dkt. No. 127 App. at 26.
[88] Ps' App. at 3, 6, 247, 249, 285, 290.
[89] *Id.* at 336.
[90] *Id.* at 332.
[91] *See id.* ("Feed-thrus were tested for helium penetration, however they were not tested for moisture (water) penetration."); D's Mot. at 14 n.7 ("Advanced Bionics did not do the hydrostatic pressure test or the soak test when it qualified the Astro Seal feed-thru.").
[92] Plaintiffs filed a Supplemental Response on March 8, 2010, which states the results of additional testing on the devices performed by their expert, Thomas J. Green, and bolsters their position that moisture caused the device failures. Bionics' Supplemental Reply challenges Mr. Green's findings and asserts that they should be excluded.

2. Breach of Express Warranty

Plaintiffs claim that Bionics breached the express warranty that it owed to them by representing that the cochlear impacts were within PMA specifications.[93] To prove breach of an express warranty, a plaintiff must show:

> (1) an express affirmation of fact or promise by the seller relating to the good
> (2) that such affirmation of fact or promise became a part of the basis of the bargain
> (3) that Plaintiff relied upon said affirmation of fact or promise
> (4) that the goods failed to comply with the express warranty
> (5) that Plaintiff was injured by such failure of the product to comply with the express warranty and
> (6) that such failure was the proximate cause of Plaintiff's injury.[94]

Bionics' "Replacement Credit Policy" (the "Policy") warranted that the implants are "free from defects in workmanship and materials and will not fail in the environment of the human body for a period of 10 years from the date of implantation."[95] Evidence shows both that the devices were defective and that they failed in the human body after being implanted for approximately one year. The exclusive remedy under the Policy was a full credit equal to the original purchase price, to be applied to the purchase of a similar cochlear implant, which was offered in lieu of any other warranty, including an implied warranty of merchantability.[96] Bionics informed B.P.'s surgeon that it would replace the devices under warranty, and Plaintiffs have not produced evidence showing that Bionics failed to offer replacement devices.[97] Plaintiffs have not produced evidence showing that Bionics made an express affirmation or

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Plaintiffs then filed objections to the Supplemental Reply. Having found other evidence showing that excessive moisture in the devices caused them to be defective, the Court does not base its decision on the supplemental filings relating to Mr. Green. Plaintiffs' Objections to Defendant Advanced Bionics' Evidence in Support of its Supplemental Reply in Support of Summary Judgment [Docket Entry #163] are, therefore, denied as moot.

[93] Compl. at ¶ 93.

[94] *McGown v. Bridgestone/Firestone, Inc.*, No. 9:05-CV-9, 2005 WL 2662572, at *4 (E.D. Tex. Oct. 18, 2005) (citing *Great Am. Prods. v. Permabond Int'l*, 94 S.W.3d 675, 681 (Tex. App.—Austin 2002, pet. denied)); *see* TEX. BUS. & COM. CODE § 2.313.

[95] Ps' App. at 283.

[96] *Id.*

[97] D's App. 12.

promise that the devices were within PMA specifications. The Court therefore grants summary judgment on Plaintiffs' breach of express warranty claim.

3. Breach of Implied Warranty of Merchantability

A disclaimer of the implied warranty of merchantability must be disclosed to the purchaser before execution of the contract of sale, unless the purchaser later agrees to the disclaimer as a modification of the contract.[98] Although the Policy disclaimed the implied warranty of merchantability, it is unclear whether the disclaimer was disclosed to the Purcels before the contract for sale was completed. During her deposition, Mrs. Purcel testified that she had never before seen the Policy and did not recognize it.[99] Although hospital records show that the Purcels were counseled about the Policy and handed a box of materials, it is unclear whether that conversation occurred before or after the sale and whether they were made aware of the disclaimer.[100] Importantly, the disclaimer was not "conspicuous," because it was not in larger type or other contrasting font or color, and is therefore ineffective.[101]

Plaintiffs have a legally and factually tenable claim that the subject devices were unreasonably dangerous and inadequate for their intended purpose. Implanting cochlear devices requires drilling of the skull, and the surgery on each ear lasts two to three hours. [102] Explanting the devices was the Plaintiffs' last resort and necessitated additional surgery.[103] As a result of problems with the devices, there is evidence both that the devices were inadequate for their

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[98] *See Dewayne Rogers Logging, Inc. v. Propac Indus., Ltd.*, 299 S.W.3d 374, 390 (Tex. App.—Tyler 2009, reh. overruled) (citing TEX. BUS. & COM. CODE § 2.316).
[99] D's App. at 85.
[100] Although B.P.'s implantation surgery occurred in July 2005, a conversation about the warranty may not have occurred until August or September of 2005. D's App. at 84.
[101] *See Fieldtech Avionics & Instruments, Inc. v. Component Control.Com, Inc.*, 262 S.W.3d 813, 828-29 (Tex. App.—Fort Worth 2008, no pet.) ("To exclude the implied warranty of merchantability, the exclusionary language must mention 'merchantability,' be in writing, and be conspicuous. . . . Language is 'conspicuous' in a disclaimer of an implied warranty if it is in larger type or other contrasting font or color.") (citing TEX. BUS. & COM. CODE § 2.316(b)).
[102] Ps' App. at 91.
[103] Ps' App. at 103.

intended purpose, because B.P. failed to reach language and developmental milestones, and unreasonably dangerous, because explanting them required additional surgery. Summary judgment is therefore denied on Plaintiffs' claim for breach of the implied warranty of merchantability.

4. Fraud and Negligent Misrepresentation

Plaintiffs' fraud and negligent misrepresentation claims are based on alleged falsehoods about the functionality and operability of the devices, and their compliance with federal law. Bionics contends that it did not make false representations and that, if it had, Plaintiffs did not rely on its false representations. The elements of fraud under Texas law are: "(1) a material representation; (2) [that] was false when made; (3) the speaker either knew it was false or asserted it without knowledge of its truth; (4) the speaker intended that it be acted upon; (5) the party acted in reliance; and (6) the party was injured as a result."[104]

Plaintiffs also assert that Bionics negligently represented that the devices were free from defect and within PMA specifications. The elements of negligent misrepresentation are:

> (1) the representation is made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest; (2) the defendant supplies "false information" for the guidance of others in their business; (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the information; and (4) the plaintiff suffers pecuniary loss by justifiably relying on the representation.[105]

Because Plaintiffs have not identified any pre-sale misrepresentation by Bionics, the fraud and negligent misrepresentation claims are limited only to misrepresentations that delayed

[104] *Malacara v. Garber*, 353 F.3d 393, 403-04 (5th Cir. 2003) (citing *Formosa Plastics Corp. USA v. Presidio Eng'rs & Contractors, Inc.*, 960 S.W.2d 41, 47 (Tex. 1998)).
[105] *Petty v. Portofino Council of Coowners, Inc.*, No. C-09-149, 2010 WL 918740, at *9 (S.D. Tex. Mar. 12, 2010) (quoting *Fed. Land Bank Ass'n v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991)).

explanting the devices.[106] There is no evidence that Bionics stated that the devices were within PMA specifications.

Plaintiffs allege three instances of fraud. On December 19, 2005, in response to reports that B.P. was humming when the external devices were activated, Bionics employees tested the functionality of B.P.'s devices, reported that the integrity of the devices was fine, and recommended programming changes.[107] Integrity testing cannot detect the presence of moisture in the HiRes90k or determine whether the devices were causing pain or discomfort.[108] As such, this representation was not fraudulent.

On or about January 9, 2006, after testing the devices at Bionics' headquarters, Bionics employees represented that programming changes could decrease humming and stated that the problem was not with the devices, but was with B.P.[109] Programming changes reduced humming, but also reduced B.P.'s sound awareness.[110]

On March 31, 2006, Bionics employees stated that there was nothing wrong with the devices and that the problem lay with B.P.[111] The only basis for Bionics' conclusions was integrity testing.[112] After the recall, Bionics represented to B.P.'s surgeon that the devices were still functional.[113]

Because integrity testing could not detect moisture in the devices, Bionics' allegedly false statements that the problem was not with the devices, but was with B.P., were made without an adequate basis to be truthful and not misleading. Bionics' response that at the time "nobody knew what was causing the problems" further shows that the alleged misrepresentations were

[106] D's App. at 100.
[107] Ps' App. at 242.
[108] *Id.* at 114-15, 120.
[109] *Id.* at 129A, 243.
[110] *Id.*
[111] *Id.* at 130.
[112] *Id.*
[113] *Id.* at 94, 297.

made without an adequate factual basis.[114] Bionics has not cited evidence supporting statements it made that B.P.'s neurologic function contributed to the failure of the devices.

Evidence shows that Bionics made these representations so that B.P. would keep the devices. An April 11, 2006 e-mail from Bionics' Director of Auditory Education and Training to other Bionics employees states: "If [the Purcels] do decide to explant-realize that given vendor B [Astro Seal] we are likely to see *moisture* and the concerns that this is 'abnormal' will be validated-a can of worms potentially . . . ."[115] Bionics also discouraged Plaintiffs' surgeon from replacing the devices.[116] Plaintiffs, who are not experts on cochlear implants, trusted and justifiably relied on Bionics' misrepresentations, which prolonged B.P.'s use of defective devices and delayed his language development skills.[117] Summary judgment is denied on Plaintiffs' fraud and negligent misrepresentation claims arising out of statements made in 2006.

CONCLUSION

For the above reasons, Bionics' Motion for Summary Judgment or Partial Summary Judgment is **GRANTED** in part and **DENIED** in part. The following claims are preempted and dismissed with prejudice: negligence by failure to warn and fraud by nondisclosure. Summary judgment is granted on the breach of express warranty claim and on the allegations that Bionics made false pre-sale statements and misrepresented that the devices were within PMA specifications. The following claims survive: negligence by violating federal law, products liability, breach of the implied warranty of merchantability, fraud, and negligent misrepresentation.

[114] D's Resp. at 19.
[115] Ps' App. at 248 (emphasis added).
[116] *Id.* at 103.
[117] *Id.* at 104.

SO ORDERED.

June 30, 2010.

BARBARA M. G. LYNN
UNITED STATES DISTRICT JUDGE
NORTHERN DISTRICT OF TEXAS